UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/644,874 | 08/21/2003 | Upvan Narang | CMED.10135 | 6850 |

45473 7590 04/05/2007
HUTCHISON LAW GROUP PLLC
PO BOX 31686
RALEIGH, NC 27612

| EXAMINER | |
|---|---|
| GHALI, ISIS A D | |
| **ART UNIT** | **PAPER NUMBER** |
| 1615 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 04/05/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/644,874 | NARANG, UPVAN | |
| | Examiner | Art Unit | |
| | Isis A. Ghali | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,7-12,15,16,21,22 and 25-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7-12,15,16,21,22 and 25-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The receipt is acknowledged of applicants' amendment field 01/10/2006.

Claims 2-6,13,14, 17-20, 23 and 24 have been canceled.

Claims 1, 7-12, 15, 16, 21, 22, 25-29 are pending and include in the prosecution.

**The following rejections have overcome by virtue of applicants' amendment and remarks:**

(A) The rejection of claims 1-29 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over any of the following patents in view of WO 97/32613 ('613) or US 5,800,803 ('803), the patents are:

Claims 1-19 of U.S. Patent No. 5,981,621, particularly claim 9,

Claims 1-50 of U.S. Patent No. 6,143,352, particularly claim 13,

Claims 1-30 of U.S. Patent No. 6,306,243, particularly claim 16,

Claims 1-7 of U.S. Patent No. 6,310,166, particularly claim 2,

Claims 1-37 of U.S. Patent No. 6,352,704, particularly claim 2,

Claims 1-47 of U.S. Patent No. 6,455,064, particularly claim 11,

Claims 1-102 of U.S. Patent No. 6,512,023, particularly claim 2,

Claims 1-76 of U.S. Patent No. 6,605,667, particularly claim 2,

Claims 1-41 of U.S. Patent No. 6,746,667, particularly claim 2.

(B) The rejection claims 1-29 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-66 of copending Application No. 09/964,415 in view of WO '613 or US '803.

(C) The rejection of claims 1-4, 7-14, 16-19, 21-24, 28-29 under 35 U.S.C. 102(b) as being anticipated by WO 99/23150 ('150).

(D) The rejection of claims 1-5, 7-12, 16-22, 28-29 under 35 U.S.C. 102(b) as being anticipated by US 6,281,265 ('265).

(E) The rejection of claims 1, 7-16, 21-29 under 35 U.S.C. 102(b) as being anticipated by US 6,310,166 ('166).

(F) The rejection of claims 1, 7-16, 21-29 under 35 U.S.C. 102(b) as being anticipated by US 6,352,704 (704).

(G) The rejection of claims 1-4, 7-19, 21-26, 28, 29 under 35 U.S.C. 102(e) as being anticipated by US 6,579,469 ('469).

(H) The rejection of claims 1, 2, 7-17, 21-29 under 35 U.S.C. 102(e) as being anticipated by US 6,585,967 ('967).

(I) The rejection of claims 1, 2, 7-17, 21-29 under 35 U.S.C. 102(e) as being anticipated by US 6,602,496 ('496)

(J) The rejection of claims 1, 2, 7-14, 16, 17, 21-24, 28, 29 under 35 U.S.C. 102(e) as being anticipated by US 6,767,552 ('552).

(K) The rejection of claims 1, 2, 7-14, 16, 17, 21-24, 28 and 29 under 35 U.S.C. 102(e) as being anticipated by US 6,942,875 ('875).

(L) The rejection of claims 1, 2, 7-17, 21-29 under 35 U.S.C. 102(e) as being anticipated by US 2004/0223946 ('946)

(M) The rejection of claims 1, 2, 7-14, 16, 17, 21-24, 28, 29 under 35 U.S.C. 102(e) as being anticipated by US 2004/0151688 ('688).

(N) The obviousness rejections presented in the previous office actions.

**The following new ground of rejections are necessitated by applicant's amendment:**

***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 7-12, 15, 16, 21, 22, 25-29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over any of the following claims 1-60 of U.S. Patent No. 6,579,469, claims 1-34 of U.S. Patent No. 6,585,967, claims 1-49 of U.S. Patent No. 6,767,552 claims 1-49 of U.S. Patent No. 6,602,496, and claims 1-36 of U.S. Patent No. 6,942,875, each in view of US 5,800,803 ('803).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and each of the issued claims are directed to adhesive composition comprising polymerizable monomer including cyanoacrylate and phenolic antimicrobial agent. The phenolic agent are recited in claim 1 of '469 patent, claim 11 of '967 patent, claim 15 of '552 patent, claim 15 of '496 patent and claim 14 of '875 patent. However, the issued patents do not claim the same antimicrobial agents as instantly claimed.

US '803 teaches antibacterial agents that are showed increased uptake to the dental tissues when combined with acrylate polymers, such antibacterial agents include chlorinated and brominated phenol compounds (abstract; col.2, lines 15-17, 44-55).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cyanoacrylate and antimicrobial agent for topical tissue application as claimed by any of the issued patents, and replace the antimicrobial phenolic compounds with any of the chlorinated and brominated phenol compounds disclosed by US '803 motivated by the teaching of US '803 that chlorophenol and bromophenol compounds show increased uptake to the dental tissues when combined with polymers, with reasonable expectation of having composition comprising cyanoacrylate and antimicrobial agent selected from chlorinated or brominated phenol compounds that has effective antimicrobial effect at the site of application.

3. Claims 1, 7-12, 15, 16, 21, 22, 25-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over -46 of copending Application No. 10/355294 and claims 1-41 of copending Application No. 10/429,050, each in view or US '803. The instant claims the conflicted claims are directed to adhesive composition comprising polymerizable monomer including cyanoacrylate monomer and phenolic antimicrobial agent applied to the skin. However, conflicted claims do not recite the same phenolic antimicrobial agents as instantly claimed.

US '803 teaches antibacterial agents that are showed increased uptake to the dental tissues when combined with acrylate polymers, such antibacterial agents include chlorinated and brominated phenol compounds (abstract; col.2, lines 15-17, 44-55).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cyanoacrylate for tissue application as disclosed by conflicted claims, and replace the phenolic compound with any of the chlorinated and brominated phenol compounds as disclosed by US '803 motivated by the teaching of US '803 that chlorophenol and bromophenol compounds show increased uptake to the dental tissues when combined with polymers, with reasonable expectation of having composition comprising cyanoacrylate and antimicrobial agent selected from chlorinated or brominated phenol compounds that has effective antimicrobial effect at the site of application.

This is a provisional obviousness-type double patenting rejection.

### *Response to Arguments*

4. Applicant's arguments filed 01/10/2007 have been fully considered but they are not persuasive. Applicants argue that the rejections are improper obviousness-type double patenting rejection because it is not focused on the claims of prior issued patent to Applicants and relies upon the further combination of prior art patents that are not commonly owned or under an obligation of assignment to Applicant. In obvious type double patenting, determining the scope and content of a patent/copending application claim relative to a claim in the application at issue is required.

In response to this argument, it is argued that using a secondary reference to establish obviousness type double patenting rejection is acceptable procedure used by the patent office. Nowhere MPEP stated that the secondary reference has to be commonly owned by applicants. The scope of the claims of the present application, and the scope of the issued patents, as well as scope of copending application, has been determined and found to be directed to the same subject matter that is drawn to composition comprising cyanoacrylate and antimicrobial phenolic agent. The subject matter claimed in the instant application is fully disclosed in the referenced patents and copending applications when combined with US '803 and would be covered by the patents and any patent granted on the copending applications.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for composition comprising octyl-cyanoacrylate monomer and triclosan, does not reasonably provide enablement for all the polymerizable monomers and all the antimicrobial agents, and all the phenolic compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

**The nature of the invention:** The nature of the invention is composition comprising polymerizable monomer and antimicrobial agent, and method of its production.

**The breadth of the claims:** The claims are very broad. The complex nature of the claims is exacerbated by the breadth of the claims. The claims encompasses myriad of monomer and myriad of antimicrobial agents including all the phenolic compounds.

**The state of the prior art:** The state of the art does not recognize all composition comprising any polymerizable polymers and any antimicrobial compounds. The state of the art recognizes acrylate monomers and antimicrobial compounds.

**The relative skill of those in the art:** The relative skill of those in the art is high.

**The amount of direction or guidance presented:** The guidance given by the specification on polymerizable polymers other than cyanoacrylate and antimicrobial

agent other than triclosan is absent. Guidance for composition comprising octyl cyanoacrylate and triclosan is provided. It is not obvious from the disclosure of octyl-cyanoacrylate and triclosan if the other polymerizable monomer and all other antimicrobial agents will work. *In re Dreshfield*, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." The article "Broader than the Disclosure in Chemical Cases," 31 J.P.O.S. 5, by Samuel S. Levin covers this subject in detail. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

**The predictability or unpredictability of the art:** The lack of significant guidance from the specification or prior art with regard to composition comprising polymerizable monomer and antimicrobial agent, other than octyl cyanoacrylate and triclosan makes practicing the claimed invention unpredictable in the terms of using other polymerizable monomer and other antimicrobial agents in all the different possible combinations.

**The presence or absence of working examples:** The specification discloses only octyl-cyanoacrylate and triclosan in example 1. No working examples to show using any other monomer with any of the other claimed antimicrobial agents. Therefore, the specification has only enabled octyl-cyanoacrylate and triclosan.

**The quantity of experimentation necessary**: Therefor, the practitioner would turn to trial and error experimentation to practice the instant invention directed to composition comprising polymerizable monomer and antimicrobial agent, and method of its making without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

***Response to Arguments***

7. Applicant's arguments filed 01/10/2007 have been fully considered but they are not persuasive. Applicants argue that the claims as amended specify the identity of the monomer and the anti-microbial agents.

In response to this argument, the claims as amended are very broad because cyanoacrylate are broad class of adhesives, and the claimed antimicrobial compounds are broad. Applicants provided guidance for composition comprising octyl cyanoacrylate and triclosan only. It is noted that the claims as amended excluded the exemplified cyanoacrylate and the exemplified antimicrobial compound. Applicants excluded octyl cyanoacrylate and triclosan from the claims. It is not obvious from the disclosure of octyl-cyanoacrylate and triclosan if the other cyanoacrylate monomers and all other phenol antimicrobial agents will work in term of different combinations.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 7, 12, 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expression "substantially" does not set forth the metes and bounds of the claim. Recourse to the specification does not define the expression "substantially".

***Response to Arguments***

10. Applicant's arguments filed 01/10/2007 have been fully considered but they are not persuasive. Applicant argues that the term "substantially" is understood by those of ordinary skill in the art reading each claim. With respect to claims 7 and 21, the term "substantially" is used to indicate that no significant amount of monomer has begun to polymerize for at least five minutes after forming the composition. In claim 12 the term indicates that presence of the antimicrobial does not materially impact the rate of polymerization of the composition.

In response to this argument, and upon careful review to the specification, it was found that the term "substantially" is not defined in the specification a defined by applicants. The metes and the bound of the term "substantially" is not define in the specification.

### *Claim Rejections - 35 USC § 102*

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1, 7-12, 16, 21-22, 28-29 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,455,033 ('033).

US '033 disclosed composition comprising curable polymerizable monomer and antimicrobial o-benzoyl-p-chlorophenol compound (abstract; col.5, lines 37-39; col.6, lines 15-20). The period of stability of the composition is inherent.

### *Response to Arguments*

13. Applicant's arguments filed 01/10/2007 have been fully considered but they are not persuasive. Applicants argue that US '033 does not disclose the claimed combination because it is directed to preparation of artificial nails. In contrast, the claimed combination is a monomeric adhesive composition.

In response to this argument, applicants attention is directed to the scope of the present claims that are drawn to composition, method of its making and method its use comprising the step of application to the tissues. Therefore, even the use claims does not require specific site for application, and does not exclude application to the nails.

Further applicants attention is directed to the teaching of US '033 where it disclosed acrylic monomer in the abstract; and claims alkylcyanoacrylate by claim 7, 6th line of claim 7. The limitations of the rejected claims are met by the reference.

### *Claim Rejections - 35 USC § 103*

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claim 1, 7-12, 16, 21, 22, 26, 28, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US WO 99/23150 ('150), US 6,281,265 ('265), US 6,310,166 ('166), US 6,352,704 (704), US 6,579,469 ('469), US 6,585,967 ('967), US 6,602,496 ('496), US 6,942,875 ('875), US 2004/0223946 ('946), and US 2004/0151688 ('688), each in view of US 5,800,805 ('803).

WO '150 teaches composition comprising cyanoacrylate and chlorophenol that form film when applied to the tissues (abstract; page 5, lines 20-25; page 7, lines 25; page 14, lines 29-30). The period of stability of the composition is inherent.

US '265 teaches composition comprising curable polymerizable monomer and antimicrobial triclosan that polymerize in situ (abstract; col.6, lines 34, 54-60; col.7, lines 17-30, 60-63; col.9, lines 6-7). The period of stability of the composition is inherent.

US '166 teaches sterile adhesive composition comprising cyanoacrylate monomer and phenol compound (abstract; col.11, line 58). The period of stability of the composition is inherent. The composition is made by placing the mixture of polymerizable cyanoacrylate monomer and phenol in container, close and sealing the container, and sterilizing the mixture and the container using heat or gamma irradiation (col.5, lines 6-48).

US '704 teaches sterile adhesive composition comprising cyanoacrylate monomer and phenol compound (abstract; col.9, line 43). The period of stability of the composition is inherent. The composition is made by placing the mixture of polymerizable cyanoacrylate monomer and phenol in container, close and sealing the container, and sterilizing the mixture and the container using heat or gamma irradiation (col.4, lines 14-60).

US '496 teaches composition comprising cyanoacrylate and chlorophenol compound (abstract; col.3, lines 63-66; col.21, lines 3-6; table II). The composition is made by placing a mixture of the ingredients in container and phenol, close and sealing the container, and sterilizing the mixture and the container (abstract). The composition is stable for 24 hours (col. 5, lines 10-25).

US '967 teaches composition comprising cyanoacrylate and phenol compound (abstract; col.6, lines 26, 63;). The composition is made by placing a mixture of the ingredients in container and phenol, close and sealing the container, and sterilizing the mixture and the container using heat or gamma irradiation (abstract; col.9, lines 25-50). The period of stability of the composition is inherent.

US '496 teaches composition comprising cyanoacrylate and phenol compound (abstract; col.12, lines 45, 57; col.13, line 50). The composition is made by placing a mixture of the ingredients in container and phenol, close and sealing the container, and sterilizing the mixture and the container using heat or gamma irradiation (col.9, lines 41-53). The period of stability of the composition is inherent.

US '875 teaches composition comprising curable polymerizable monomer and phenol compound (abstract; col.13, lines 17-20; col.14, line 10). The period of stability of the composition is inherent.

US '946 teaches composition comprising cyanoacrylate and phenol compound (abstract; paragraphs 0022, 0023; 0052, 0053; claims 8, 17). The composition is made by placing a mixture of the ingredients in container and phenol, close and sealing the container, and sterilizing the mixture and the container using heat or gamma irradiation (col.9, lines 41-53). The composition is stable for 1 year (paragraph 0043).

US '688 teaches composition comprising curable polymerizable monomer and phenol compound (abstract; paragraphs 0017, 0039, 0044claims 6, 17). The period of stability of the composition is inherent.

However, each of the references does not teach the specific antimicrobial agents as claimed by claim 1.

US '803 teaches antibacterial agents that are showed increased uptake to the dental tissues when combined with acrylate polymers, such antibacterial agents include chlorinated and brominated phenol compounds (abstract; col.2, lines 15-17, 44-55).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cyanoacrylate and antimicrobial agent as disclosed by any of WO '150, US '265, US '166 or US '704, US '469, US '967, US '496, US '875, US '946, US '688 and replace the antimicrobial agent by brominated phenol compounds disclosed by US '803, motivated by the teachings of US '803 that bromophenol compounds show increased uptake to the dental tissues when combined with polymers, with reasonable expectation of having composition comprising cyanoacrylate and brominated phenol compounds that has effective antimicrobial effect at the site of application.

16. Claims 15, 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of any of WO 150, US '265, US '033, US '875, US '688 each in view of US '803, and further in view of US '166.

The combined teachings of WO 150, US '265, US '033, US '875, or US '688 each with US '803 are discussed above. However, the combination of the references do not teach the composition is sterile, which is taught by US '166.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cyanoacrylate and antimicrobial agent as disclosed by the combined teachings of any of WO '150, US '265, US '033, US '875, or US '688 each with US '803, and further sterilize the composition as disclosed by US '166, motivated by the teaching of US '166 that sterilization shows low levels of tissue toxicity, with reasonable expectation of having

safe sterile composition comprising cyanoacrylate and antimicrobial that exhibits no tissue toxicity.

17. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '469 in view of US '166.

The teachings of the reference are discussed above. US '469 does not teach the method of sterilizing the composition, which is taught by US '166.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cyanoacrylate and antimicrobial agent as disclosed by any of WO '150, US '265, and further sterilize the composition by heat or gamma irradiation as disclosed by US '166, motivated by the teaching of US '166 that sterilization shows low levels of tissue toxicity, with reasonable expectation of having safe sterile composition comprising cyanoacrylate and antimicrobial that exhibits no tissue toxicity.

18. Claims 1, 7-12, 16, 21, 22, and 28-29 are rejected under 35 U.S.C. 103(a) as being obvious over US 6,455,064 ('064) or US 6,746,667 ('667) each in view and US '803.

The references teach polymer composition comprising cyanoacrylate and antimicrobial agent for wound closure.

The references do not teach chlorophenol and bromophenol as antimicrobial agents in the composition, which are disclosed by US '803.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cyanoacrylate for tissue application as disclosed by any of the references, and replace the antimicrobial agent with any of the chlorinated and brominated phenol compounds as disclosed by US '803 motivated by the teaching of US '803 that bromophenol compounds show increased uptake to the dental tissues when combined with polymers, with reasonable expectation of having composition comprising cyanoacrylate and antimicrobial agent selected from chlorinated or brominated phenol compounds that has effective antimicrobial effect at the site of application.

19. Claims 15, 25-27 are rejected under 35 U.S.C. 103(a) as being obvious over any of US '064 and US '667 each in view of US '803 and further in view of US '166.

The teachings of US '064 and US '667 in view of US '803 are discussed above. The combination of the references does not teach the method of making the composition and its sterilization, which is taught by US '166.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cyanoacrylate and antimicrobial agent as disclosed by the combined teaching of US '064 or US '667 with US '803, and further sterilize the composition by heat or gamma irradiation as disclosed by US '166, motivated by the teaching of US '166 that sterilization shows low levels of tissue toxicity, with reasonable expectation of having safe sterile composition comprising cyanoacrylate and antimicrobial that exhibits no tissue toxicity.

***Response to Arguments***

20. Applicant's arguments filed 01/10/2007 have been fully considered but they are not persuasive. Applicant traverses the obviousness rejections by arguing that:

- U.S. Patent Nos. 6,579,469, 6,585,967 6,602,496, 6,942,875, 2003/0082116, 2004/0223946, 2004/0151688, 6,455,064, 6,512,023, 6,605,667 and 6,746,667 are not properly cited in rejections under 35 U.S.C. §103 because they are only prior art under 35 U.S.C. §102(e) and were owned by the same person or subject to an obligation of assignment to the same person at the time the invention was made.

In response to this argument, it is argued that applicants did not overcome the rejection over these patents because this rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing

that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2). Applicant failed to do so.

- Applicants further argue that it would not have been obvious to one of ordinary skill in the art to combine the recited references to arrive to the present invention.

In response to this argument, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the primary references all teach antimicrobial agent, and US '803 teaches the specific antimicrobial agent, and one having ordinary skill in the art would have replaced the antimicrobial agent of any of the primary references by brominated phenol compounds disclosed by US '803, motivated by the teachings of US '803 that bromophenol compounds show increased uptake to the dental tissues when combined with polymers, with reasonable expectation of having composition comprising cyanoacrylate and brominated phenol compounds that has effective antimicrobial effect at the site of application. US '166 is relied upon for teaching sterile composition and method of its sterilization. In considering the disclosure of the reference, it is proper to take into

account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

***Conclusion***

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis A Ghali
Primary Examiner
Art Unit 1615

IG

Isis Ghali

ISIS GHALI
PRIMARY EXAMINER